ACAREXX- ivermectin suspension
Boehringer Ingelheim Vetmedica, Inc.

Acarexx®
(0.01% ivermectin)
Otic Suspension

NADA 141-174, Approved by FDA

Caution:

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Description:

Chemical name: Ivermectin is a mixture of 5-*O*-demethyl-22,23-dihydroavermectin A_{1a} (component B_{1a}) and 5-*O*-demethyl-25-de (1-methylpropyl)-22,23-dihydro-25-(1-methylethyl) avermectin A_{1b} (component B_{1b}). Empirical formula: $B_{1a} = C_{48}H_{74}O_{14}$, $B_{1b} = C_{47}H_{72}O_{14}$. Molecular weight: B_{1a} = 875.10, B_{1b} = 861.07.

Indications:

Acarexx (0.01% ivermectin) Otic Suspension is indicated for the treatment of adult ear mite *(Otodectes cynotis)* infestations in cats and kittens four weeks of age or older. Effectiveness against eggs and immature stages has not been proven.

Dosage:

Acarexx suspension is administered topically in the ear canal at an ivermectin concentration of 0.01%. One dose of 0.5 mL is applied in each ear. Repeat treatment one time if necessary, based upon the ear mite life cycle and the response to treatment.

Administration:

Tear foil pouch at the notch to remove the two plastic ampules. Use one ampule per ear. Shake well before use. Snap off the cap of the ampule and place the tip into the external ear canal. Squeeze the entire contents of one ampule into the ear and massage the base of the ear to distribute the medication. Repeat the procedure in the other ear using the second ampule. In clinical field trials, ears were not cleaned and many animals still had debris in their ears at the end of the study. Cleaning the ears prior to administration of Acarexx suspension is not necessary to provide effectiveness.

Human Warnings:

Not for human use. Keep out of reach of children.

Precautions:

The safe use of Acarexx suspension in cats used for breeding purposes, during pregnancy, or in lactating queens, has not been evaluated.

Adverse Reactions:

In approximately 1% of 80 cats and kittens, pain associated with the pinna and vomiting were observed following treatment with Acarexx suspension.

To report suspected adverse reactions, to obtain a Material Safety Data Sheet or for technical assistance, call 1-866-638-2226.

Effectiveness:

One treatment with Acarexx suspension was 92% effective in treating adult ear mite *(Otodectes cynotis)* infestations after seven days in a dose titration/confirmation study. In a well-controlled clinical field trial, one treatment of Acarexx suspension was 94% effective in clearing cats and kittens of adult ear mite infestations within 7 to 10 days.

Safety:

In two Target Animal Safety studies, Acarexx suspension was proven to be safe in kittens four weeks of age or older. Four-week-old kittens were administered Acarexx suspension at dose rates of 1X, 3X and 5X the recommended dose for three or six consecutive days and no adverse reactions were observed, except one kitten treated at 1X the dose had histologic evidence of minimal, chronic dermal inflammation of the ear. In a well-controlled clinical field trial, Acarexx suspension was used safely in cats and kittens receiving other frequently used veterinary products such as flea control products, vaccines, anthelmintics, antibiotics and steroids.

Storage:

Store below 86°F (30°C). Protect from freezing.

How Supplied:

Acarexx Otic Suspension is packaged in two polypropylene ampules per foil pouch, which are packaged 12 foil pouches per display carton. Each ampule is filled to deliver 0.5 mL of 0.01% ivermectin otic suspension per ear.

Manufactured for:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.

Acarexx is a registered trademark of Boehringer Ingelheim Vetmedica, Inc.

449701-01
Code 449711
Revised 10/2011

83664909

83663228, R.0

Laminate Pouch, Front

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Laminate Pouch, Back

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St. Joseph, MO 64506 U.S.A.

449702-03 Code 449711
83664909
83663155, R.1
B8F1

Display Carton

NDC 0010-4497-02

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(0.01% ivermectin)

Otic Suspension

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Net Contents: 12 foil pouches containing 2 ampules per pouch. Each ampule contains 0.5 mL of 0.01% ivermectin otic suspension.

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Boehringer Ingelheim

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ACAREXX

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Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:0010-4497
Route of Administration	AURICULAR (OTIC)	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)	IVERMECTIN	0.1 mg in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0010-4497-02	12 in 1 CARTON		
1	NDC:0010-4497-01	2 in 1 POUCH		
1		0.5 mL in 1 AMPULE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141174	03/26/2014	

Labeler - Boehringer Ingelheim Vetmedica, Inc. (007134091)

Registrant - Boehringer Ingelheim Vetmedica, Inc. (007134091)

Revised: 4/2014 Boehringer Ingelheim Vetmedica, Inc.